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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,332	02/25/2002	Robert A. Dixon		4092

30592 7590 11/30/2004

DONALD J. HACKMAN
3499 KIRKHAM RD
COLUMBUS, OH 43221

EXAMINER

REIP, DAVID OWEN

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,332	Applicant(s) DIXON ET AL.	
	Examiner David O. Reip	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,12,14,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,12,14,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification makes no mention of adhesive material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 12, 14, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Tornier (U.S. Pat. No. 4,488,543). Figs. 1-3 of Tornier show a bone stabilizing system having all the limitations as recited in the above listed claims, including: a plate 2, and; two or more bone screws 3, each with a threaded bone shank portion and unthreaded, tapered plate/bone shank portion 3a which inherently makes an

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"interference" fit with the corresponding tapered holes 6 in the plate. Note in Fig. 3 that since a portion of the tapered screw head 3a extends below the bottom surface of the plate, such portion would inherently extend into the screw hole in the bone in an "interference" fit.

Double Patenting

Claims 1, 3, 4, 6, 12, 27, and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,656,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims, being narrower than the application claims, constitute "species" of invention. Application claims 1, 3, 4, 6, 12, 27, and 28 are generic to the "species" of invention covered by the patent claims. Thus, the generic invention is "anticipated" by the species of the patented invention. Accordingly, absent a terminal disclaimer, claims 1, 3, 4, 6, 12, 27, and 28 are properly rejected under the doctrine of obviousness-type double patenting. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

It is noted that a Terminal Disclaimer has been filed on 8/25/04 which includes the signature of Mr. Donald Hackman. However, it is also noted that Mr. Hackman has only 50% interest in the instant application, with the other 50% interest being owned by Mr. Robert Dixon. Mr. Hackman may not sign for and disclaim the 50% interest owned by Mr. Dixon. Therefore, Mr. Dixon must provide a separately signed Terminal Disclaimer for his 50% interest.

Response to Amendment

The amendment filed 8/25/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: All the newly added, underlined text for inclusion on page 5, line 24 and page 7, line 14 detailing the use of adhesives. The original specification does not disclose adhesives or the use of adhesives in any manner. Therefore, newly added disclosure to adhesives generally and "cyanoacrylates" and "Dermabond" specifically clearly constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments filed 8/25/04 have been fully considered but they are not persuasive. Applicant argues that Tornier does not claim a taper extending into the bone. What is or is not specifically recited or claimed in Tornier does not negate the fact that Fig. 3 shows at least a portion of the tapered screw head 3a protrudes below the bottom surface of the plate 1 when the screw is fully inserted into the plate. The examiner argues, given that the bottom of the plate is flush with the bone surface, that the tapered, protruding portion of the screw head is structurally capable of penetrating into the bone screw hole at least a minimal amount, thus inherently forming an "interference" fit.

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Applicant further argues that Tornier does not mention or imply machined holes in the bone. The examiner reminds the applicant that the human body and parts thereof, including bones and holes in bones, are not considered to be patentable subject matter, as per the following:

Then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, issued a notice in the Official Gazette stating, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." 1077 OG 24 (1987), reprinted in 1146 TMOG 24 (1993).

Therefore, while the applicant may claim a method of drilling, tapping or otherwise machining holes in bone, the applicant may not, in a claim directed to an apparatus, positively recite "machined and threaded holes in the bone" (ref. claim 1) or "machined holes in the underlying bone" (ref. claim 27) in combination with the elements of the apparatus. Thus, the examiner has considered all recitations of "machined holes in the bone" (or the like) as being recitations of the intended use of the claimed apparatus. The intended use has been considered but does not serve to structurally distinguish the claimed device over the applied reference.

Applicant further argues that because Tornier includes the additional elements of the screw 9 and disk 11 that help prevent screw back-out, the screws of Tornier are not intended to be self-locking. The examiner counters that "self-locking" has not been claimed. Instead, the claims broadly recite that the bone screws "make an interference fit within the plate holes" (ref. claim 1) and "the bone screws contain one or more locking tapers" (ref. claim 3). In Tornier, it is clearly seen that the tapered screw head and the

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tapered hole in the plate form some amount of interference and frictional locking once the screw head is in its fully tightened position within the plate hole.

The applicant further argues that the Tornier plate will not fit into the space of the present invention. The examiner counters that the claims of the instant invention contain only the relatively broad recitation of intended use, "for the purpose of fixing one bone segment, within a bone column, with respect to one or more bone segments or an implant within the bone column." Tornier is specifically a femoral fracture plate, intended for fixing one bone segment within a bone column to another segment within the bone column. Therefore, Tornier meets the recited intended use.

Conclusion

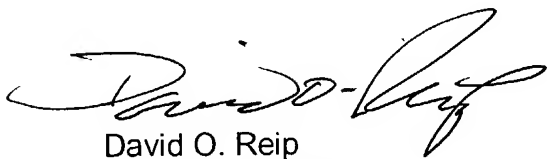
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David O. Reip
Primary Examiner
AU 3731